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TITLE:

Probiotic (VSL#3) for Gulf War Illness

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# REPORT DOCUMENTATION PAGE

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14. ABSTRACT  The overall objective of the study is to determine whether probiotic VSL#3® will improve 1) intestinal symptoms of Irritable Bowel Syndrome and 2) non-intestinal symptoms (fatigue, joint pain, insomnia, general stiffness and headache) associated with IBS. All of these symptoms are part of the Gulf War illness. We screened our first participant in September 2013. Overall we have screened 65 and 30 randomized and 9 Gulf War Veterans are waiting for arrival of study drug. Our efforts are ongoing to recruit more Gulf War veterans. The first batch of stool samples have been sent to Lawrence Berkeley Laboratory microbiota analysis.				
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**Introduction:**

Gastroenteritis plays a major role in changing intestinal microflora. More than one third of Gulf War (GW) veterans report gastroenteritis during deployment and it is a risk factor for development of irritable bowel syndrome (IBS) after deployment. We also demonstrated that there is a strong association between IBS and extra-intestinal disorders (e.g. fatigue, joint pains, insomnia, generalized stiffness, and headache). This would suggest that IBS as well as extra-intestinal disorders in GW veterans have a unifying etiology. There is scientific evidence that probiotics by restoring normal gut flora improve symptoms of IBS. Probiotics have also been shown to improve arthritis and fatigue by changing fecal flora. This is the basis for our present protocol to study the effect of probiotics on GW illness.

**Body:**

During the last on year the following goals were accomplished:

- We have screened 65 GW veterans and enrolled 30 from the beginning of the study. Of the 30 veterans enrolled in the study, 28 have completed the study. Nine Veterans are waiting to receive medications. One Veteran withdrew before starting study medication and second did not take the study medication as directed.
- The first set of stool samples have been sent to the Lawrence Berkeley laboratory for microbiota analysis.
- We received the list of Gulf War Veterans in the Salt Lake City are from the Defense Manpower Database. This increased our study population. We are in the process of requesting a second batch of list of GW Veterans. We plan to send recruitment letters to these veterans informing them about the study.
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**Key Research Accomplishments.....**

- We have recruited 30 Gulf War Veterans and 9 waiting for study medication.

**Reportable Outcomes.....**

Nil.

**Conclusion:**

Study is ongoing at a good pace as we planned. We continue our recruitment efforts to increase our study enrollment. First set of stool and blood samples will be analyzed.

**References.....**

Nil.

**Appendices.....**

Nil.